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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,641	11/28/2001	Nobuya Matsuoka	215869US0PCT	5497

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EXAMINER

COVINGTON, RAYMOND K

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/926,641

Applicant(s)

MATSUOKA ET AL.

Examiner

Raymond Covington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-8, 13, 14, 27, 28, 31-34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 13, 14, 27, 28, 31-34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 4,6,7,22,27,28, drawn to products of formula [II-1], classified in class 560, subclass 51, for example.
- II. Claims 5,39,40,44-46, drawn to products of formula [II-2], classified in class 544, subclass 382.
- III. Claims 8,13,14,34,41-43, drawn to a method of expressing long-term potentiation, classified in class 514, subclass 255.01.
- IV. Claims 31,32,33,36,3847-51,53, drawn to Screening methods and products, classified in class 436, subclass 63.
- V. Claims 37,52,54, drawn to pharmaceutical package, classified in class 424, subclass 520.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said

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method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 4-8, 13-14, 22, 27, 28, 31-34, 36-54 are generic to a plurality of disclosed patentably distinct species comprising, for example, O-heterocyclic derivatives classified in 549/200+, S-heterocyclic derivatives classified in 549/1+, polycyclic thiomorpholine derivatives classified in 544/60+, polycyclic morpholine derivatives classified in 544/101+, diazine derivatives classified in 544/224+, thiodiazine derivatives classified in 544/8+, benzothiazine classified in 544/49+, isoquinoline derivatives classified in 546/139+, tropane derivatives classified in 546/124+, oxazole derivatives classified in 548/240+, thiodiazole derivatives

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classified in 548/125+, 568/38+, 568/630+, and various other species too numerous to recite. The inventions are distinct, each from the other because of the following reasons: the compounds differ materially in structure and element so much so as to be patentably distinct. In addition, a reference, which anticipates one group, may not even render obvious the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Upon election, the Examiner will review the claims and indicate (a) a generic concept inclusive of the elected species {compounds which are so similar thereto as to be part of the elected matter} and (b) by such indication (i.e. by exclusion) which compounds are drawn to non-elected subject matter.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 5,39,40 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The specification does not give any guidance as to how each of the heterocyclic substituted piperazine derivatives were prepared. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming heterocyclic substituted amine derivatives. Applicants have not disclosed any working examples, which would demonstrate, or guide, one skilled in the art as to how the  $R^5 R^6$  heterocyclic substituted piperazine compounds were prepared or obtained. The process of making the heterocyclic substituted derivatives or how the heterocyclic substituted derivatives were obtained is not readily apparent from the specification. The specification must teach how to make the invention. *In re Gardner*, 166 U.S.P.Q. 138 (1970). In order to practice the claimed invention, one skilled in the art would have speculate how the derivatives were obtained or prepared. Therefore, the instant invention is not enabled. Claims limiting the scope of these terms should overcome this rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703) 308-4704. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Rotman can be reached on (703) 308-0204. The fax phone numbers for the organization where this application or proceeding is

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assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Raymond Covington  
Examiner  
Art Unit 1625



RKC

July 11, 2003